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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,911

Applicant(s)

HARRISON ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-15 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8,9 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 4,10,15,30-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This Office Action is a response to the "Amendment..." filed 27 May 2003 (Paper No. 18) in reply to the Non-Final Office Action mailed 16 December 2002 (Paper No. 14). Claims 23-29 were withdrawn from consideration and claims 1-22 were considered in Paper No. 14. Claims 6, 7 and 16-22 were canceled, claims 1-5 and 8-15 were amended and claims 30-32 were added in Paper No. 18. Claims 1-5, 8-15 and 23-32 are pending. Claims 1-5, 8-15 and 30-32 are under consideration.

Election/Restrictions

This application contains claims 23-29 drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The drawings stand objected to for the reasons indicated on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Response to Amendment

Rejection of claims 6, 7 and 16-22 is rendered moot by cancellation of the claims.

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Claim Rejections - 35 USC § 112

Rejection of claims 1-5 and 8-15 under 35 U.S.C. 112, first paragraph, as lacking adequate written description is withdrawn in view of the amendments.

Rejection of claims 4, 10 and 15 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendments to the claims.

Rejection of 1-3, 5, 8, 9 and 11-14 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in part and maintained in part for reasons of record and set forth herein below in the response to arguments.

Rejection of claim 5 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in view of the amendments.

Claim Rejections - 35 USC § 102

Rejection of claims 1, 4, 10 and 11 under 35 U.S.C. 102(a) as anticipated by Jiang *et al.* (1999) *Diabetes* 48:722-730 (IDS #9) and claims 1 and 12 under 35 U.S.C. 102(b) as anticipated by either one of Kerr-Conte *et al.* (1996) *Diabetes* 1108-1114 or Dudek (1990) U.S. Patent No. 4,935,000 is withdrawn in view of the amendment of the claims such that they are now limited to methods comprising culturing pancreatic epithelial cells in the presence of bone morphogenetic

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protein. The art of record does not teach or suggest culturing pancreatic epithelial cells in the presence of bone morphogenetic protein.

Response to Arguments

Claims 1-3, 5, 8, 9 and 11-14 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of stimulating or otherwise facilitating formation of colonies of mammalian pancreatic cells comprising culturing pancreatic cells in the presence of laminin-1 or in the presence of laminin-1 and BMP 6/6, BMP 7/7 and BMP 4/7, does not reasonably provide enablement for any method comprising culturing pancreatic cells in the absence of laminin-1, or in the presence of any and all functional derivatives, homologues, mimetics, analogues or agonists of BMP and laminin-1. In response, Applicant has amended the claims such that they are now limited to a method comprising culturing pancreatic cells in the presence of a bone morphogenetic protein. Although it was previously indicated that the claims were only enabled for BMP 6/6, BMP 7/7 and BMP 4/7, upon further consideration, it is clear that the specification would enable the skilled artisan to determine which bone morphogenetic proteins can be used in the method without engaging in undue experimentation.

However, as pointed out in the previous office action, Jiang *et al.* (2002) *J. Cell Sci.* 115:753-760 teach that the BMPs tested therein did not facilitate formation of colonies of pancreatic cells containing insulin in the absence of laminin-1 (see especially the final paragraph on page 754). The skilled artisan would therefore have to engage in undue experimentation to identify a BMP or other culture conditions that would enable the method in the absence of laminin-1. Applicant cites teachings on page 14 of the specification (lines 1-5 and 25-31) as

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enabling for practicing the methods in the absence of laminin-1. However, these teachings are merely prophetic and provide no guidance that would enable the skilled artisan to overcome the art recognized failure of BMP to induce the formation of three-dimensional cystic-ductular structures containing insulin-secreting cells in the absence of laminin-1. Therefore, in order to practice the full scope of the claimed method, the skilled artisan would have to resort to blind trial and error experimentation to identify additional culture conditions that would enable the method in the absence of laminin-1. Clearly the amount of experimentation would be beyond the routine. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for any method comprising culturing pancreatic cells in the absence of laminin-1.

Allowable Subject Matter

Claims 4, 10, 15 and 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
July 31, 2003



JAMES KETTER
PRIMARY EXAMINER